

Exhibit 4

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April 29, 2011

BY EXPRESS U.S. MAIL & E-MAIL

Donald M. Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue, SW
Suite 314G
Washington, District of Columbia 20201
Donald.Berwick@CMS.hhs.gov

Re: United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Actavis Mid Atlantic, et al. -
Civil Action No. 08-10852-PBS, MDL No. 1456

Dear Dr. Berwick:

This firm represents defendant Sandoz Inc. ("Sandoz") in the above-referenced action, which is a *qui tam* lawsuit brought under the federal False Claims Act by Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") regarding Medicaid drug price reporting. I write to request, on behalf of Sandoz and its co-defendants in this action, the oral deposition testimony of the Centers for Medicare and Medicaid Services ("CMS") concerning the areas of inquiry noticed in the subpoena served on CMS on April 14, 2011. A copy of the subpoena is attached hereto as Exhibit A.

In a letter dated April 21, 2011, counsel for CMS objected to the subpoena on the grounds that it did not comply with 45 C.F.R. §§ 2.1-2.6 (the "Touhy regulations"). Sandoz does not believe the subpoena implicates the Touhy regulations here, as it was directed to CMS as an entity under Federal Rule of Procedure 30(b)(6), and not to any particular CMS "employee," which is the subject of the Touhy regulations, *see* 45 C.F.R. § 2.1(a).¹ Nevertheless, to avoid a dispute on this issue, and without conceding the applicability of the Touhy regulations here, Defendants make

¹ Moreover, there is authority suggesting that the procedures set forth under analogous Touhy regulations are not mandated in connection with a subpoena for a Rule 30(b)(6) deposition. *See Orange Env't, Inc. v. County of Orange*, 145 F.R.D. 320, 324 (S.D.N.Y. 1992).

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the requests for testimony set forth below. Given the discovery schedule in this case, we respectfully request that you make a decision on our request on or before **May 6, 2011**. We are, of course, willing to work with CMS to find mutually agreeable dates for the requested deposition.

Section 2.4(a) of the Code of Federal Regulations provides that requests for testimony “must state the nature of the requested testimony, why the information sought is unavailable by any other means, and why the testimony would be in the interest of the DHHS or the federal government.” For the reasons set forth below, and for the reasons previously explained to and already in the possession of CMS and its counsel, CMS should allow the requested testimony.

1. Nature of the Requested Testimony

Defendants request the testimony of CMS regarding their drug pricing information, including without limitation Average Manufacturer Prices (AMPs), provided in connection with pharmaceutical products under Medicaid. (Exhibit A, Area of Inquiry 1.) Included in this request is testimony regarding any analysis, evaluation, review of or reliance by CMS on any representation regarding such information provided by Defendants. (*Id.*)

Defendants also request the testimony of CMS concerning CMS’s and the federal government’s policies and decisions to encourage the dispensing of generic drugs under Medicaid. (*Id.*, Area of Inquiry 2.)

Finally, Defendants request the testimony of CMS regarding CMS’s consideration, approval, or disapproval of Section 4.19(b) of proposed or actual amendments to state Medicaid plans submitted under 42 U.S.C. § 1396(a), including proposed or actual amendments that include State Maximum Allowable Cost Programs (SMAC Programs) and proposed or actual amendments that include differential Estimated Acquisition Cost (EAC) calculations between branded or single-source pharmaceutical products and generic or multi-source pharmaceutical products. (*Id.*, Area of Inquiry 3.) Included in this request is testimony regarding specific State Plan Amendments for eleven states. (*Id.*)

2. Availability through Other Means

The information that Defendants request is not available through other means.

With regard to Defendants’ request for testimony regarding their AMPs and other pricing information, CMS is uniquely positioned to provide relevant testimony. The federal government has required pharmaceutical manufacturers to provide their AMPs and relies on such information in connection with the Medicaid rebate program, and CMS has specifically approved State Plan Amendments that provide for reimbursement based on pricing information supplied by certain of the Defendants, such as AWP and WACs. CMS’s understanding of and rationale to permit the use of such information is available only through CMS. Moreover, such pricing information is specific to Defendants and has not been the subject of prior depositions of CMS officials.

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Similarly, CMS is uniquely positioned to provide testimony concerning its and the federal government's policies and decisions to encourage the dispensing of generic drugs under Medicaid. Such testimony is not available from Ven-A-Care or other third parties and is not available through other means. Moreover, any prior deposition testimony CMS officials may have given regarding generic drugs is not sufficient to address the unique issues raised in this particular litigation as they pertain to those Defendants.

Testimony concerning CMS's consideration, approval, or disapproval of proposed and actual State Plan Amendments likewise is unavailable through other means. CMS is the sole agency responsible for the approval of Medicaid State Plan Amendments, and only it can provide the information it took into account, the rationale it applied, and the decisions it made with regard to proposed State Plan Amendments. Such information is not sufficiently reflected in the State Plan documents themselves or the related written correspondence or deposition testimony produced to date. Finally, Defendants in this cases have not had any meaningful opportunity to ask CMS questions with respect to the unique issues raised in this litigation.

3. Interests of DHHS and the Federal Government

It is in the interest of DHHS and the federal government to provide the testimony requested by Defendants. Ven-A-Care is alleging violations of the federal False Claims Act for overpayments that the federal government allegedly made in connection with pharmaceutical reimbursements under the Medicaid program. The federal government is a party in interest in this case, and the requested testimony goes directly to the federal government's understanding of and decisions with regard to the reimbursement system under Medicaid, which are crucial issues in this action. It is in the interest of the federal government to permit a complete record to be established on these and other issues and that the jury have a full understanding of the relevant facts in this case.

Moreover, providing this testimony is in the interest of DHHS and the federal government because it avoids unwarranted litigation to obtain it. If the agency decides to withhold the requested information, Defendants may have no choice but to engage in motion practice before the Court in order to obtain testimony to establish meritorious defenses in this case.

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For the foregoing reasons, Defendants request that you authorize the requested testimony as soon as possible, and in any event, no later than May 24, 2011.

Sincerely,



Paul B. Carberry

Enclosure

Donald Berwick, M.D.

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cc: William B. Schultz, Esq. (by e-mail to William.Schultz@hhs.gov)
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